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PCT Application  
PCT/JP2003/008791

PATENT COOPERATION TREATY

PCT

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

10/520784

Translation

Applicant's or agent's file reference 3085WO0P	<b>FOR FURTHER ACTION</b> See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/JP2003/008791	International filing date (day/month/year) 10 July 2003 (10.07.2003)	Priority date (day/month/year) 11 July 2002 (11.07.2002)
International Patent Classification (IPC) or national classification and IPC C07D 471/04, A61K 31/437, 31/444, 31/5377, 31/541, A61P 13/00, 13/02, 13/10, 25/04, 29/00, 43/00		
Applicant TAKEDA CHEMICAL INDUSTRIES, LTD.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of <u>5</u> sheets, including this cover sheet.  <input type="checkbox"/> This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).  These annexes consist of a total of <u>          </u> sheets.
3. This report contains indications relating to the following items:  I <input checked="" type="checkbox"/> Basis of the report II <input type="checkbox"/> Priority III <input checked="" type="checkbox"/> Non-establishment of opinion with regard to novelty, inventive step and industrial applicability IV <input type="checkbox"/> Lack of unity of invention V <input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement VI <input type="checkbox"/> Certain documents cited VII <input type="checkbox"/> Certain defects in the international application VIII <input type="checkbox"/> Certain observations on the international application

Date of submission of the demand 11 August 2003 (11.08.2003)	Date of completion of this report 11 December 2003 (11.12.2003)
Name and mailing address of the IPEA/JP	Authorized officer
Facsimile No.	Telephone No.

# INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/JP2003/008791

## I. Basis of the report

### 1. With regard to the elements of the international application:\*

- ☒ the international application as originally filed
- ☐ the description:  
 pages \_\_\_\_\_, as originally filed  
 pages \_\_\_\_\_, filed with the demand  
 pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_
- ☐ the claims:  
 pages \_\_\_\_\_, as originally filed  
 pages \_\_\_\_\_, as amended (together with any statement under Article 19  
 pages \_\_\_\_\_, filed with the demand  
 pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_
- ☐ the drawings:  
 pages \_\_\_\_\_, as originally filed  
 pages \_\_\_\_\_, filed with the demand  
 pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_
- ☐ the sequence listing part of the description:  
 pages \_\_\_\_\_, as originally filed  
 pages \_\_\_\_\_, filed with the demand  
 pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_

### 2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language \_\_\_\_\_ which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

### 3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

### 4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages \_\_\_\_\_
- ☐ the claims, Nos. \_\_\_\_\_
- ☐ the drawings, sheets/fig \_\_\_\_\_

### 5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).\*\*

\* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rule 70.16 and 70.17).

\*\* Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

# INTERNATIONAL PRELIMINARY EXAMINATION REPORT

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## III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application.

☒ claims Nos. 8-17

because:

☒ the said international application, or the said claims Nos. 14, 15  
relate to the following subject matter which does not require an international preliminary examination (*specify*):

See supplemental sheet

☒ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. 8-13, 16, 17  
are so unclear that no meaningful opinion could be formed (*specify*):

See supplemental sheet

☐ the claims, or said claims Nos. \_\_\_\_\_ are so inadequately supported  
by the description that no meaningful opinion could be formed.

☒ no international search report has been established for said claims Nos. 14, 15

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the standard.

☐ the computer readable form has not been furnished or does not comply with the standard.

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**Supplemental Box**

(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: III.1

Claims 14 and 15

The inventions that are set forth in claims 14 and 15 pertain to methods for the treatment of the human body by therapy.

Claims 8-13, 16 and 17

The range of the structures that are included within the scope of the term "prodrug" as set forth in the claims cannot be said to be clear even in the light of the disclosures in the description; therefore, the scope of the compounds and the medicinal drugs that are set forth in the present application is unclear.

Consequently, the description and claims 8-13, 16 and 17 do not comply with the given requirements to such an extent as to make it possible to carry out a meaningful international search.

The international search report was created on the basis of a search of prior art documents in relation to the compounds that are specifically set forth in the description; as a result, the international preliminary examination was carried out in relation to the same range of compounds as the international search.

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.  
PCT/JP 03/08791**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

## 1. Statement

Novelty (N)	Claims	1-13, 16, 17	YES
	Claims		NO
Inventive step (IS)	Claims	1-13, 16, 17	YES
	Claims		NO
Industrial applicability (IA)	Claims	1-13, 16, 17	YES
	Claims		NO

## 2. Citations and explanations

Document 1: JP 2001-513551 A

Document 2: JP 2002-511866 A

The inventions that are set forth in claims 1-13, 16 and 17 are novel and involve an inventive step in relation to documents 1 and 2 cited in the international search report. The compounds that are set forth in the present application are vanilloid receptor agonists that have a unique chemical structure, and said compounds are not disclosed or suggested in documents 1 and 2.